

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA : Criminal No. 06-
 :
 v. : 18 U.S.C. §§ 371, 1341,
 : 1343, 1957 & 2
 CHARLENE CYNTHIA DEMARCO, and :
 ELIZABETH LERNER, a/k/a :
 "Elizabeth Copperman," a/k/a :
 "Liza" : I N D I C T M E N T

The Grand Jury in and for the District of New Jersey,
sitting in Camden, charges:

COUNT 1

(Conspiracy to Commit Mail and Wire Fraud)

The Defendants

1. At all times relevant to this Indictment:

a. Defendant CHARLENE CYNTHIA DEMARCO was a Doctor of Osteopathy specializing in the treatment of Lyme Disease, a disease contracted by humans through contact with ticks. In particular, defendant DEMARCO treated patients with severe cases of Lyme disease, as well as patients suffering from adverse reactions to Lyme Disease vaccines.

b. Defendant CHARLENE CYNTHIA DEMARCO maintained an office and residence at 462 Philadelphia Avenue, Egg Harbor City, New Jersey, in the District of New Jersey.

c. Defendant ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," was at no time a medical professional.

d. From at least as early as in or about August 2002, defendant ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," resided at 462 Philadelphia Avenue, Egg Harbor City, New Jersey, in the District of New Jersey. Defendant Lerner purported to be an assistant to defendant CHARLENE CYNTHIA DEMARCO.

The Food and Drug Administration

2. At all times relevant to this Indictment:

a. The United States Food and Drug Administration ("FDA") was the federal agency within the United States Department of Health and Human Services charged with the responsibility for protecting the health and safety of the American public by ensuring that drugs are safe and effective for their intended uses before they may be legally introduced into interstate commerce. Drugs within the FDA's purview included articles intended for use in the diagnosis, cure, mitigation, treatment, and prevention of disease in humans and articles intended for use as components of any such articles.

b. An investigational new drug was a new or biological drug that was used in clinical investigation. An Investigational New Drug Application ("IND") was a formal request for approval from the FDA for the introduction of such an

investigational drug into interstate commerce for the purpose of conducting required clinical studies.

Amyotrophic Lateral Sclerosis

3. Amyotrophic Lateral Sclerosis ("ALS"), commonly known as "Lou Gehrig's Disease," is a debilitating neurodegenerative disease affecting the upper and lower motor neurons. The disease is characterized by the progressive deterioration and loss of these motor neurons. The loss of nerve stimulus to specific muscles results in muscular atrophy and progressive weakness that leads to paralysis. There is little known about the causes of ALS and even less known about its cure. The length of survival in most patient populations that have been evaluated is approximately three to five years from the onset of symptoms.

Patient "M.S."

4. Beginning in or about September 2000, defendant CHARLENE CYNTHIA DEMARCO oversaw the care of "M.S.," a patient previously diagnosed with ALS.

5. In or about December 2001, defendant CHARLENE CYNTHIA DEMARCO contacted a staff member at the FDA concerning the use of stem cells for the treatment of M.S.'s ALS. Stem cells are unspecialized cells that can be induced under certain

circumstances to become cells with specialized functions, such as the cells of the heart muscle that cause it to beat or the cells of the pancreas that produce insulin. At that time, the FDA staff member informed defendant DEMARCO that she had to submit an IND to the FDA before taking any action towards the proposed stem cell treatment for M.S.'s ALS.

6. On or about January 5, 2002, defendant CHARLENE CYNTHIA DEMARCO submitted an IND ("IND1") to the FDA seeking approval to treat M.S.'s ALS by injecting stem cells into the base of M.S.'s brain. On or about January 29, 2002, defendant DEMARCO received a telephone call from FDA staff seeking additional information for IND1, including a justification for the risk the proposed procedure presented to M.S. On or about February 8, 2002, defendant DEMARCO received another telephone call from FDA staff seeking additional information to support IND1. On or about February 13, 2002, defendant DEMARCO withdrew IND1 from consideration by the FDA.

7. On or about March 18, 2002, defendant CHARLENE CYNTHIA DEMARCO submitted a second IND ("IND2") to the FDA for the treatment of M.S.'s ALS with stem cells. In IND2, defendant DEMARCO proposed placing stem cells on a layer of gel-foam to be injected onto the surface of M.S.'s brain, from which the stem cells could be absorbed. On or about April 9, 2002, the FDA placed IND2 on hold, meaning that defendant DEMARCO could not

conduct the proposed procedure until the FDA received additional information from defendant DEMARCO and conducted a further review of IND2.

8. On or about May 9, 2002, defendant CHARLENE CYNTHIA DEMARCO was notified by a letter from the FDA that IND2 was on hold and that clinical trials could not begin under IND2. On or about June 26, 2002, defendant DEMARCO faxed the FDA an amendment to IND2. On or about July 5, 2002, DEMARCO received a notice from the FDA reminding her that IND2 remained on hold. On or about July 15, 2002, July 18, 2002 and July 25, 2002, defendant DEMARCO submitted additional information to the FDA. On or about August 16, 2002, defendant DEMARCO was notified by a letter from the FDA that IND2 remained on hold and that she still had not submitted sufficient information to justify the risk to the patient from the proposed procedure. On or about that same day, defendant DEMARCO had a telephone call with a representative of the FDA who reiterated to defendant DEMARCO that IND2 remained on hold.

9. On or about August 16, 2002, defendant CHARLENE CYNTHIA DEMARCO falsely informed M.S.'s family that the FDA had approved the proposed stem-cell treatments for M.S.'s ALS. Defendant DEMARCO further advised M.S.'s family that M.S. would be transported from New Jersey to Illinois for surgery on August 19, 2002.

10. On or about August 17, 2002, M.S. died. Defendant CHARLENE CYNTHIA DEMARCO provided no stem-cell treatment to M.S. before M.S.'s death.

The Conspiracy

11. From at least as early as in or about October 2002 to in or about November 2004, in the District of New Jersey and elsewhere, defendants

CHARLENE CYNTHIA DEMARCO
and
ELIZABETH LERNER,
a/k/a "Elizabeth Coppermann,"
a/k/a "Liza,"

knowingly and wilfully conspired and agreed with each other and with others, to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, which scheme and artifice was in substance as set forth below, and for the purpose of executing such scheme and artifice (i) delivered and caused to be delivered by United States Postal Service and private and commercial interstate carrier according to the direction thereon, matters and things, contrary to Title 18, United States Code, Section 1341, and (ii) transmitted and caused to be transmitted by means of wire communications in interstate commerce, writings, signs, signals, and sounds, contrary to Title 18, United States Code, Section 1343.

Object of the Conspiracy

12. It was the object of the conspiracy that defendants CHARLENE CYNTHIA DEMARCO and ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," acting for their own financial gain, falsely represented that defendant DEMARCO could treat ALS patients with stem cell therapy in order to induce the patients' families to pay for such treatment, although defendant DEMARCO would not provide, and could not have provided, the promised treatment.

Manner and Means

13. It was part of the conspiracy that defendants CHARLENE CYNTHIA DEMARCO and ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," falsely represented to ALS patients and their families that defendant DEMARCO could provide stem cell treatments for ALS.

14. It was further part of the conspiracy that defendants CHARLENE CYNTHIA DEMARCO and ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," opened numerous bank and money management accounts in their own names and in the name of a newly formed company, Innovative Cellular Technology ("ICT"), into which they deposited funds received from the ALS patients' families.

15. It was further part of the conspiracy that defendants CHARLENE CYNTHIA DEMARCO and ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," accepted payments from ALS patients' families for stem cell treatments, even though no such treatments were, or could have been, provided by defendant DEMARCO.

16. It was further part of the conspiracy that the defendants CHARLENE CYNTHIA DEMARCO and ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," diverted the money from the ALS patients's families to their personal use.

17. It was further part of the conspiracy that, as a result of the above acts, defendants CHARLENE CYNTHIA DEMARCO and ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," defrauded victims of money and property.

Overt Acts

18. In furtherance of the conspiracy and to effect its unlawful object, defendants CHARLENE CYNTHIA DEMARCO and ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," committed and caused to be committed the following overt acts in the District of New Jersey and elsewhere:

Patient "R.P."

a. On or about October 31, 2002, defendant CHARLENE CYNTHIA DEMARCO spoke by telephone with "R.P.," a patient residing in Louisiana recently diagnosed with ALS, and R.P.'s spouse about treatment for R.P.'s ALS and/or Lyme disease.

b. In or about November 2002, defendant CHARLENE CYNTHIA DEMARCO falsely represented to R.P. and R.P.'s spouse that she had previously received FDA approval to treat ALS using stem cells for a patient named "M," and suggested that she provide stem cell treatment for R.P.'s ALS.

c. On or about January 16, 2003, defendant CHARLENE CYNTHIA DEMARCO transmitted by interstate wire an electronic mail message to R.P.'s spouse indicating that defendant DEMARCO was moving forward with an IND requesting FDA approval of stem cell treatment for R.P.'s ALS, and noting that her associate, "Elizabeth Coppermann," would contact the family and should be trusted.

d. On or about April 3, 2003, defendant ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," transmitted by interstate wire an electronic mail message to R.P.'s spouse falsely stating that defendants LERNER and CHARLENE CYNTHIA DEMARCO had received stem cells for treatment of R.P.'s ALS.

e. On or about April 18, 2003, defendant CHARLENE CYNTHIA DEMARCO transmitted by interstate wire an electronic mail

message to R.P.'s spouse falsely claiming that stem cell treatments for R.P.'s ALS were about to begin.

f. On or about May 7, 2003, defendant CHARLENE CYNTHIA DEMARCO opened bank account number 0283036, at the First National Bank of Absecon in Absecon, New Jersey, under her own name (the "Absecon Bank Account").

g. On or about May 14, 2003, defendant CHARLENE CYNTHIA DEMARCO caused R.P.'s spouse to approve the transfer of \$5,190 from R.P.'s spouse's bank account in Louisiana to the Absecon Bank Account.

Patient "T.T.B."

h. In or about February 2004, defendant CHARLENE CYNTHIA DEMARCO spoke by telephone with a relative of "T.T.B.," a patient diagnosed with ALS residing in Louisiana, and explained that she could provide stem cell treatments for T.T.B.'s ALS.

i. On or about February 17, 2004, defendant CHARLENE CYNTHIA DEMARCO transmitted by interstate wire an electronic mail message replying to an electronic mail message from a relative of T.T.B. that referenced the family's efforts to raise funds to pay for DEMARCO's proposed stem-cell treatments for T.T.B.'s ALS.

j. On or about April 21, 2004, defendant CHARLENE CYNTHIA DEMARCO spoke by telephone to family members of T.T.B.

regarding the cost of the proposed stem cell treatment for T.T.B.'s ALS.

k. On or about April 22, 2004, defendant CHARLENE CYNTHIA DEMARCO caused to be delivered from a relative of T.T.B. in Kinder, Louisiana, by United States Postal Service Express Mail, a check for \$35,000 payable to the order of "Charlene DeMarco" to pay for stem-cell treatment of T.T.B.'s ALS, addressed to defendant DEMARCO in New Jersey.

l. On or about May 3, 2004, defendant CHARLENE CYNTHIA DEMARCO caused to be delivered from New Jersey by Federal Express a "cost analysis" purporting to show the expenses of treating T.T.B.'s ALS with stem cells, addressed to T.T.B. in Louisiana.

m. On or about May 5, 2004, defendants CHARLENE CYNTHIA DEMARCO and ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," opened account number 794-11583, at Merrill Lynch under defendant LERNER's name (the "Lerner Account").

n. On or about May 10, 2004, defendant CHARLENE CYNTHIA DEMARCO endorsed the \$35,000 check received from T.T.B.'s relative to the benefit of defendant ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," for deposit into the Lerner Account.

Patient "C.M."

o. In or about May 2004, defendant CHARLENE CYNTHIA DEMARCO spoke by telephone with a relative of "C.M.," a patient residing in Louisiana diagnosed with ALS, regarding the possibility of stem cell treatments for C.M.'s ALS.

p. On or about June 12, 2004, defendant CHARLENE CYNTHIA DEMARCO spoke by telephone to C.M. and C.M.'s family, explaining that she was operating an on-going study of stem cell treatments for ALS patients and that she required an up-front fee of \$35,000 for such treatments.

q. On or about June 20, 2004, defendant CHARLENE CYNTHIA DEMARCO caused to be delivered from a family member of C.M. in Louisiana, by United States Mail, a check for \$35,000 payable to the order of "Innovative Cellular Technology, c/o Elizabeth Lerner," addressed to defendant DEMARCO in New Jersey.

r. On or about June 30, 2004, defendants CHARLENE CYNTHIA DEMARCO and ELIZABETH LERNER, a/k/a "Elizabeth Coppermann," a/k/a "Liza," opened account number 794-07200 in the name of Innovative Cellular Technology ("ICT") at Merrill Lynch and deposited C.M.'s check for \$35,000 into the ICT account.

Patient "W.G."

s. On or about July 9, 2004, defendant CHARLENE CYNTHIA DEMARCO spoke by telephone with a family member of

"W.G.," a patient diagnosed with ALS residing in Louisiana, and discussed the possibility of stem cell treatments for W.G.'s ALS, noting that the worst result the family could expect was that the treatments would be ineffective.

t. On or about August 1, 2004, Defendant CHARLENE CYNTHIA DEMARCO spoke by telephone with W.G. and family, informing the family that stem-cell treatment for W.G.'s ALS required a \$35,000 up-front fee.

In violation of Title 18, United States Code, Section 371.

COUNTS 2 - 4
(Mail Fraud)

1. Paragraphs 1 through 10, and 12 through 17 of Count 1 of this Indictment are hereby realleged and incorporated as though set forth in full herein.

2. On or about the following dates, at the following locations, in the District of New Jersey and elsewhere, defendants

CHARLENE CYNTHIA DEMARCO
and
ELIZABETH LERNER
a/k/a "Elizabeth Coppermann,"
a/k/a "Liza,"

did knowingly and willfully devise and intend to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, as described in paragraphs 12 through 17 of Count 1.

3. For the purpose of executing the aforesaid scheme and artifice, in the District of New Jersey and elsewhere, defendants

CHARLENE CYNTHIA DEMARCO
and
ELIZABETH LERNER
a/k/a "Elizabeth Coppermann,"
a/k/a "Liza,"

did knowingly and willfully cause to be delivered by United States Postal Service and private and commercial interstate

carrier, as described below, according to the directions thereon
the following:

<u>Count</u>	<u>Date</u>	<u>From</u>	<u>To</u>	<u>Via</u>	<u>Item</u>
2	4/22/04	Kinder, LA	Egg Harbor City, NJ	U.S. Postal Service	\$35,000 T.T.B. check to DeMarco
3	6/20/04	Johnson Bayou, LA	Egg Harbor City, NJ	U.S. Postal Service	\$35,000 C.M. check to ITC, c/o Lerner
4	5/3/04	Egg Harbor City, NJ	Kinder, LA	Federal Express	"Cost Analysis"

In violation of Title 18, United States Code, Sections 1341
and 2.

COUNTS 5-10
(Wire Fraud)

1. Paragraphs 1 through 10, and 12 through 17, of Count 1 of this Indictment are hereby realleged and incorporated as though set forth in full herein.

2. On or about the following dates, at the following locations, in the District of New Jersey and elsewhere, defendants

CHARLENE CYNTHIA DEMARCO
and
ELIZABETH LERNER
a/k/a "Elizabeth Coppermann,"
a/k/a "Liza,"

did knowingly and willfully devise and intend to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, as described in paragraphs 12 through 17 of Count 1.

3. For the purpose of executing the aforesaid scheme and artifice, in the District of New Jersey and elsewhere, the defendants

CHARLENE CYNTHIA DEMARCO
and
ELIZABETH LERNER
a/k/a "Elizabeth Coppermann,"
a/k/a "Liza,"

did knowingly and willfully transmit and cause to be transmitted by means of wire in interstate and foreign commerce the following writings, signs, signals, pictures and sounds:

<u>Count</u>	<u>Date</u>	<u>From</u>	<u>To</u>	<u>Wire Transmission</u>
5	1/16/03	DeMarco	R.P.'s spouse	Email re: progress of IND for R.P. and introduction of "Coppermann"
6	4/3/03	Lerner	R.P.'s spouse	Email re: stem cells received
7	4/18/03	DeMarco	R.P.'s spouse	Email re: stem cell treatments for R.P.'s ALS will begin soon
8	2/17/04	DeMarco	T.T.B.'s family member	Email re: fund-raising
9	6/12/04	DeMarco	C.M. & family members	Telephone call re: stem cell treatment study; \$35,000 up-front fee
10	7/9/04	DeMarco	W.G.'s family member	Telephone call re: treatment options; risk

In violation of Title 18, United States Code, Sections 1343 and 2.

Count 11
(Money Laundering)

1. Paragraphs 1 through 10, and 12 through 17, of Count 1, and paragraph 1 of Counts 2 through 4 of this Indictment are hereby realleged and incorporated as though set forth in full herein.

2. On or about May 10, 2004, in the District of New Jersey and elsewhere, defendants

CHARLENE CYNTHIA DEMARCO
and
ELIZABETH LERNER
a/k/a "Elizabeth Coppermann,"
a/k/a "Liza,"

did knowingly engage and attempt to engage in a monetary transaction in criminally derived property of a value greater than \$10,000, namely the deposit into Merrill Lynch account number 794-11583 in the name of "Elizabeth Lerner" of a \$35,000 check, which funds were derived from a specified unlawful activity, namely conspiracy to commit mail and wire fraud, contrary to Title 18, United States Code, Section 371, and mail fraud, contrary to Title 18, United States Code, Section 1341.

In violation of Title 18, United States Code, Sections 1957

and 2.

A TRUE BILL

FOREPERSON

CHRISTOPHER J. CHRISTIE
UNITED STATES ATTORNEY